L: 4410-09-P

DEPARTMENT OF JUSTICE Drug Enforcement Administration

[Docket No. 22-5] Jennings Staley, M.D.; Decision and Order

On October 8, 2021, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause (OSC) to Jennings Staley, M.D., (Respondent) of California, alleging that Respondent "committed such acts that would render [his] registration inconsistent with the public interest." OSC, at 2 (citing 21 U.S.C. 823(f) and 824(a)(4)).

A hearing was held before DEA Administrative Law Judge Paul E. Soeffing (the ALJ) who, on June 10, 2022, issued his Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision (RD).^{2,3} Having reviewed the entire record, the Agency adopts and hereby incorporates by reference the entirety of the ALJ's rulings, credibility findings,⁴ findings of fact, conclusions of law, sanctions analysis, and recommended sanction found in the RD.

I. FINDINGS OF FACT

The material facts in this case are narrow and undisputed. At the start of the COVID-19 pandemic, Respondent began a "concierge medicine program" providing telemedicine, home

¹ The Government sought to revoke Respondent's Certificates of Registration Nos. FS8992794 (909 Prospect Street, Suite 100C, La Jolla, CA 92037), FS7111519 (31888 Del Obispo Street, Suite C2, San Juan Capistrano, CA 92675), FS7522508 (420 Palladio Parkway, Suite 123, Folsom, CA 95630), FS4937922 (5016 Chesebro Road, Suite 210, Agoura Hills, CA 91301), and FS7568718 (23600 Rockfield Boulevard, Suite 2N, Lake Forest, CA 92630) and sought to deny Respondent's pending applications for new DEA Registrations Control Nos. W21025364C (24251 Town Center Drive, Suite 175, Valencia, CA 91355) and W21018406C (corrected) (13728 Hesperia Rd, Suite 7, Victorville, CA 92395). OSC, at 1-2.

² The RD, which is summarized herein, found in favor of the Government and neither party filed exceptions.

³ After the RD was issued, but before the deadline for filing exceptions had passed, Respondent notified the ALJ that he voluntarily surrendered his five DEA Certificates of Registration, but that the two applications were still pending. See Notice of Surrender dated June 30, 2022. Where a registration is terminated pursuant to 21 CFR 1301.52 after an ALJ has transmitted a recommended decision for final agency action (or, as here, after the ALJ had made all of the findings and recommendations), the Agency determines, on a case-by-case basis, if a final adjudication is warranted or if the matter should be dismissed. See Steven M. Kotsonis, M.D., 85 FR 85,667, 85,668-69 (2020); The Pharmacy Place, 86 FR 21,008 (2021); Creekbend Community Pharmacy, 86 FR 40,627 n.4 (2021). Here, the Agency will continue to adjudicate this case because the final official record of the allegations, the evidence, and the final agency decision will all support the Agency's future interactions with Respondent; further, adjudication is necessary to address the two pending applications. See Cypress Creek Pharmacy LLC, 86 FR 71,927 n.2 (2021) (citing Lawrence E. Stewart, M.D., 86 FR 15,257 (2021)).

⁴ The Agency agrees that the assigned DEA Diversion Investigator's (DI) testimony was credible; Respondent's testimony was not fully credible and at times irrelevant, conflicting, and defensive; and Amanda Staley's (Respondent's wife and medical assistant) testimony was largely irrelevant. RD, at 4, 10, 12.

visits, and delivery of COVID-19 medication packages to people at risk of developing COVID-19. Tr. 92, 180; *see also Id.* at 93-96, 106, 181, 185, 192. In April 2020, an undercover FBI agent (UC) asked for six COVID-19 medication packages for himself and his family.

Government Exhibit (GX) 8, at 2-3. At that point, Respondent, unsolicited, offered to dispense Xanax⁵ to UC. *Id.* at 4-5 ("Resp: And then you need any Xanax? UC: Yeah, um why not? Yeah, I mean sounds great."). Respondent testified that he offered to dispense Xanax "as a courtesy" because UC seemed anxious. Tr. 143. UC later told Respondent's wife that he had talked to Respondent, that he was approved for the concierge medical program, and that Respondent had said that he could have Xanax.⁶ Tr. 172. Respondent's wife then packaged the order, including the Xanax, and shipped it to UC's home. *Id.* at 172-73. Respondent testified that he believed he had no further conversations with UC after the Xanax shipped. *Id.* at 35-41, 173, 187, 207; GX 8, 10, 11, 12. Respondent admitted that he had not completed a medical evaluation nor diagnosed UC with a condition that would warrant dispensing Xanax, but still provided UC with the Xanax. *Id.*; *see also*, GX 10.8

II. DISCUSSION

The Government has the burden of proving that the requirements for revocation of a DEA registration in 21 U.S.C. 824(a) are satisfied. 21 CFR 1301.44(e). Having reviewed the record, the Agency agrees with the RD that the Government has proven by substantial evidence that Respondent committed acts which render his continued registration inconsistent with the public interest. RD, at 12-18, 22. Specifically, the Agency agrees with the RD that the record

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⁵ The parties stipulated that Xanax is a brand name for alprazolam, a Schedule IV controlled substance. RD, at 2.

⁶ DI testified that during the course of his investigation, he did not become "aware of any prescription that was written by [Respondent] for this medication," *id.* at 51, nor has Respondent argued that there was a prescription for the Xanax. *See* Resp Posthearing, at 8.

⁷ When asked, "Had you diagnosed patient BM with any condition that would warrant taking alprazolam?" Tr. 207, Respondent answered, "No sir. I had not done a medical evaluation on patient BM." *Id.* Respondent then answered "Yes," to the question "but you nonetheless provided him with alprazolam, correct?" *Id.* at 207-08.

⁸ On July 21, 2021, Respondent entered a guilty plea in the United States District Court for the Southern District of California for violating 18 U.S.C. 541, wherein he admitted that he "offered [UC] Viagra and Xanax without collecting any medical information about the undercover agent or the agent's purported family members . . . and his staff then mailed six treatment packs to the undercover agent, which included . . . Xanax" GX 10, at 4.

established multiple instances where Respondent failed to comply with applicable federal and state law and dispensed controlled substances in a manner inconsistent with the public interest.

DEA regulations require that for a prescription for a controlled substance to be effective, it must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice. 21 CFR 1306.04(a). CA Bus. & Prof. Code § 2242(a) prohibits prescribing or dispensing dangerous drugs dangerous drugs dangerous drug absent an appropriate physical exam and medical indication. Here, Respondent admitted that he mailed Xanax, a "dangerous drug" under California law, to UC without conducting any physical examination or diagnosing UC "with any condition that would warrant taking [Xanax]." Tr. 207; see also CA Bus. & Prof. Code § 4022. This admitted conduct clearly violated California law and rendered Respondent's dispensing outside the usual course of professional practice. Furthermore, DEA regulations state that a practitioner may only provide Schedule IV controlled substances to a patient without a prescription where the practitioner administers or dispenses the controlled substance directly to the patient. 21 CFR 1306.21(b). Here, the record evidence shows that Respondent violated 21 CFR 1306.21(b) because he neither issued a valid prescription for nor directly dispensed the Xanax pills that he mailed to UC. See supra n.6.

Accordingly, the Agency agrees with the RD that the Government has established by substantial evidence that Respondent issued Xanax to Respondent in violation of CA Bus. & Prof. Code § 2242, and 21 CFR 1306.04(a) and 1306.21(b). RD, 17-18. As such, the Agency finds that Respondent's continued registration is inconsistent with the public interest and, thus, that the Government has established a *prima facie* case for revocation and denial. *Id*.

III. SANCTION

Here, the Government has established grounds to revoke Respondent's registration, so

⁹ California law defines the term "dispense" to mean "the furnishing of drugs or devices upon a prescription from a physician . . ." and states that "[f]urnish means to supply by any means, by sale or otherwise." CA Bus. & Prof. Code §§ 4024, 4026.

 $^{^{10}}$ CA Bus. & Prof. Code § 4022 defines the term "dangerous drug" to "mean any drug . . . that bears the legend . . . "Rx only" . . . [or] that by federal or state law can be lawfully dispensed only on prescription." Here, the alprazolam bottle that Respondent mailed to UC contained the marking "RX Only." GX 9.

the burden shifts to Respondent to show why he can be entrusted with the responsibility carried by a registration. *Garret Howard Smith, M.D.*, 83 FR 18,882, 18,910 (2018). When a registrant has committed acts inconsistent with the public interest, he must both accept responsibility and demonstrate that he has undertaken corrective measures. *Holiday CVS, L.L.C., dba CVS Pharmacy Nos 219 and 5195*, 77 FR 62,316, 62,339 (2012).

Here, Respondent has failed to unequivocally accept responsibility. *See* RD, at 19-20. Instead, Respondent justified his conduct and even attempted, unsuccessfully, to establish that his shipping of Xanax to UC was proper. ¹¹ *Id.* at 19-20. Respondent's misconduct was also egregious. ¹² *See Garrett Howard Smith, M.D.*, 83 FR at 18,910 (collecting cases). Respondent, unsolicited, offered free Xanax to UC and then shipped it for UC and his whole family to use ¹³ without a prior medical examination or valid prescription. GX 8, at 4. This conduct lacks even a veneer of a legitimate medical purpose and is more closely aligned with that of a drug dealer than that of a doctor. Any sanction less than revocation would send a message to the current and prospective registrant community that serious violations of the core principals of the CSA will not result in revocation, so long as the violation represents only a single incident. *See Daniel A. Glick, D.D.S.*, 80 FR 74,800, 74,810 (2015).

Having reviewed the record in its entirety, the Agency finds that Respondent cannot be entrusted with a DEA registration and orders that his registration be revoked.

ORDER

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a), I hereby revoke DEA Certificates of Registration Nos. FS8992794, FS7111519, FS7522508,

¹¹ The Respondent even seemed incredulous that DEA was pursuing this matter. *See* RD, at 19-20 (citing Tr. 75-76). Moreover, when a registrant fails to make the threshold showing of acceptance of responsibility, the Agency need not address the registrant's remedial measures. *Ajay S. Ahuja, M.D.*, 84 FR 5479, 5498 n.33 (2019). Even so, here, "Respondent made no showing of any remedial measures he has undertaken." RD, at 20.

¹² Respondent argued that his misconduct was not egregious enough to support revocation because the Government only established "a single incident, involving an anti-anxiety medication which is not prone to abuse or overdose," and pointed out that he did not profit from shipping the Xanax. Resp Posthearing, at 7. The Agency disagrees and finds that Respondent's blatant disregard for the laws relating to controlled substances warrants a sanction.

¹³ Respondent testified that though the Xanax was only dispensed in UC's name, it was for all "eligible members of the family . . . him, his wife, his [father-in-law], and in an unusual situation, possibly a child." Tr. 214-15.

FS4937922, and FS7568718 issued to Jennings Staley, M.D. Further, pursuant to 28 CFR

0.100(b) and 21 U.S.C. 823(f), I hereby deny any pending applications for renewal or

modification of these registrations, deny Respondent's applications for new DEA Registrations

Control Nos. W21025364C and W21018406C, and deny any other pending application of

Jennings Staley, M.D., for registration in California. This order is effective [INSERT DATE

THIRTY DAYS FROM DATE OF PUBLICATION IN THE FEDERAL REGISTER].

SIGNING AUTHORITY

This document of the Drug Enforcement Administration was signed on December 12,

2022, by Administrator Anne Milgram. That document with the original signature and date is

maintained by DEA. For administrative purposes only, and in compliance with requirements of

the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has

been authorized to sign and submit the document in electronic format for publication, as an

official document of DEA. This administrative process in no way alters the legal effect of this

document upon publication in the Federal Register.

Heather Achbach,

Federal Register Liaison Officer,

Drug Enforcement Administration.

[FR Doc. 2022-27480 Filed: 12/19/2022 8:45 am; Publication Date: 12/20/2022]